IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SHAFFER PHARMACY, INC., THOMAS TADSEN, AND WILSON BUNTON, Defendants.	)	CASE NO.: 3:21 CV 22 MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION **FILED EX PARTE AND TEMPORARILY UNDER SEAL**

Over the past five years, Defendants, Shaffer Pharmacy, Inc., Thomas Tadsen, and Wilson Bunton, illegally dispensed powerful opioid painkillers and other controlled substances pursuant to prescriptions with no legitimate medical purpose and not issued in the usual course of professional practice. Defendants crossed the legal line between professional practice and violating the Controlled Substances Act ("CSA"). The United States files this action to stop Defendants illegal dispensing as soon as possible.

The CSA authorizes the Attorney General "to commence a civil action for appropriate declaratory or injunctive relief relating to" any violation. 21 U.S.C. § 843(f). As the attached evidence shows, Defendants' actions over the past five years have fed opioid addiction in

Northern Ohio and contributed to the nation's opioid epidemic. Absent immediate relief, Defendants will be free to continue illegally dispensing controlled substances and inflicting further harm on the community. To protect the public, the United States moves for a temporary restraining order and preliminary injunction under 21 U.S.C. §§ 843(f) and 882(a), and Federal Rule of Civil Procedure 65(a)-(b), to immediately cease Defendants' illegal dispensations.

I. BACKGROUND

A. THE CONTROLLED SUBSTANCES ACT

The CSA establishes "a closed regulatory system" under which it is "unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). All controlled substances are categorized onto one of five schedules "based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body." *Raich*, 545 U.S. at 13; *see* 21 U.S.C. § 812 (schedules I through V).

Accordingly, the CSA requires those who manufacture, distribute, or dispense controlled substances to obtain a registration from the United States Drug Enforcement Administration ("DEA"). *See* 21 U.S.C. § 822(a). A pharmacy that fills controlled substance prescriptions for patients "dispenses" them within the meaning of the CSA and must register with DEA. *Id.* § 802(10) (defining "dispense" as "to deliver a controlled substance to an ultimate user [i.e., a patient] . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing . . . of a controlled substance"); *see also id.* § 802(21) (defining a practitioner to include a "pharmacy . . . licensed, registered, or otherwise permitted . . . to distribute [or] dispense . . . a controlled substance in the course of professional practice"). A pharmacy registered with DEA may only dispense or distribute controlled substances "to the extent authorized by [the pharmacy's] registration and in conformity with the" CSA. 21 U.S.C. § 822(b).

The CSA limits a prescriber's authority to prescribe in that prescriptions may not be issued without "a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice." 21 C.F.R. § 1306.04. *See also United States v. Volkman*, 797 F.3d 377, 392 (6th Cir. 2015); *United States v. Moore*, 423 U.S. 122, 140 (1975).

The CSA also limits pharmacists' authority to fill prescriptions. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a). Furthermore, a pharmacy that knowingly fills "a prescription issued not in the usual course of professional treatment . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.* *See also United States v. Leal*, 75 F.3d 219, 227 (6th Cir. 1996) (holding that both the CSA and 21 C.F.R. § 1306.04 impose a duty on pharmacists) (abrogated on other grounds by *United States v. Kennedy*, 107 Fed. Appx. 518 (6th Cir. 2004)). In addition, "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice . . . ." 21 C.F.R. § 1306.06. Both the pharmacy and the individual pharmacist may be held liable for filling prescriptions that were not issued in the usual course of professional practice and for a legitimate medical purpose. *United States v. Appalachian Regional Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1189-90 (E.D. Ky. 2017) (there is "nothing inconsistent about articulating the responsibilities of individual practitioners and pharmacists while simultaneously indicating that other entities may be subject to penalties for their role in issuing and filling invalid prescriptions"). *See also Advance Pharmaceutical, Inc. v. United States*, 391 F.3d 377 (2d Cir. 2004); *United States v. Green Drugs*, 905 F.2d 694 (3d Cir. 1990); *United States v. Poulin*, 926 F. Supp. 246, 252-53 (D. Mass. 1996).

B. DEFENDANTS

Shaffer Pharmacy, Inc. is a retail pharmacy in Toledo, Ohio. Meredith Carter Decl. ¶ 24. Shaffer Pharmacy is owned by Thomas Tadsen, a pharmacist; he has owned and operated Shaffer Pharmacy for over 40 years. *Id.* ¶ 25. Shaffer Pharmacy has its own DEA registration number: AS8550243. *Id.* ¶ 29. As a pharmacy registered with the DEA, Shaffer Pharmacy is permitted to dispense schedule II, III, IV, and V controlled substances. *See* 21 U.S.C. § 822(b).

Defendant Tadsen is a Registered Pharmacist and was first licensed as a pharmacist in Ohio in or around August 1977 and has owned Shaffer Pharmacy since 1979. Carter Decl. ¶ 25.

Defendant, Wilson Bunton, is a pharmacist at Shaffer Pharmacy. *Id.* ¶ 26. Defendant Bunton was first licensed as a pharmacist in Ohio in or around June 2016. *Id.* He has worked at Shaffer Pharmacy since around October 2017. *Id.*

II. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 65(a)-(b), the Court's inherent equitable authority, and the CSA, the United States seeks a temporary restraining order and a preliminary injunction to prohibit Defendants from dispensing controlled substances. This Court may grant injunctive relief under 21 U.S.C. § 843(f)(1) to remedy Defendants' violations of 21 U.S.C. § 842(a)(1) for unlawful dispensing, as alleged in the Complaint. *See* Compl. ¶¶ 101-105. Also, 21 U.S.C. § 882(a) provides authority to enjoin Defendants' CSA violations.

The government seeks a temporary restraining order and preliminary injunction. To obtain a temporary restraining order, issuing without notice, the government must show the factors to support a preliminary injunction, and that "immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition." Fed. R. Civ. P. 65(b)(1)(A); *see, e.g.*, *Midwest Retailer Associated, Ltd. v. City of Toledo*, 563 F. Supp. 2d 796, 802 (N.D. Ohio 2008).

Traditionally, courts weighing a preliminary injunction motion consider whether (1) the movant has established a strong likelihood of success on the merits; (2) the movant would suffer irreparable injury without the injunction; (3) substantial harm to others would result; and (4) the public interest would be served by the injunction. *Doe v. Univ. of Cincinnati*, 872 F.3d 393, 399 (6th Cir. 2017); *City of Pontiac Retired Emps. Ass'n v. Schimmel*, 751 F.3d 427, 430 (6th Cir. 2014) (en banc). But "when a court is called upon to enforce a federal statutory injunction, its reliance upon the traditional practices of equity must be conditioned by the necessities of the public interest which Congress has sought to protect." *United States v. City of Painesville*, 644 F.2d 1186, 1193 (6th Cir. 1981) (quotation omitted). Because the CSA "is a Congressional Act to protect the public health, the Government only needs to establish that [the defendant] violated the statute and there is some cognizable danger of recurrent violation." *United States v. S. Serra Cheese Co.*, No. 14-13077, 2015 WL 6156961, at *6 (E.D. Mich. Oct. 20, 2015); *see, e.g.*, *City of Painesville*, 644 F.2d at 1193-94; *United States v. Am. Mercantile Corp*, 889 F. Supp. 2d 1058, 1083 (W.D. Tenn. 2012).

Regardless of the test, the United States must prove—and the attached evidence sufficiently demonstrates—that Defendants violated the CSA by dispensing controlled substances pursuant to prescriptions issued outside the usual course of professional practice and without any legitimate medical purpose. To protect its patients and the public, the Court should issue a temporary restraining order immediately.

III. THE EVIDENCE SHOWS DEFENDANTS VIOLATED THE CSA

On at least thousands of occasions from January 1, 2015 through February 20, 2020, Defendants dispensed controlled substances in violation of 21 U.S.C. § 842(a)(1). Section 842(a)(1) makes it illegal for a person "who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title." Part C covers the

requirements relating to registration of manufacturers, distributors, and dispensers of controlled substances. *See generally* 21 U.S.C. §§ 821-832.

Subject to two exceptions not relevant here, sections 829(a) and (b) generally require that no controlled substance in schedules II, III, IV, or V be dispensed except upon a practitioner's "prescription." A prescription issued without "a legitimate medical purpose" and outside "the usual course of [] professional practice" is not lawfully a prescription. 21 C.F.R. § 1306.04(a). The practitioner is responsible for "proper prescribing . . . , but a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* A prescription may only be filled by a pharmacist "acting in the usual course of his professional practice . . . ." 21 C.F.R. § 1306.06.

Here, Defendants routinely filled prescriptions for large quantities of dangerous opioid painkillers, including fentanyl, and other controlled substances without any legitimate medical purpose. Thus, and as described below, Defendants violated section 842(a)(1) of the CSA because: (1) the CSA's registration requirements apply to it; (2) it distributed or dispensed scheduled controlled substances that are prescription drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"); and (3) its pharmacists violated their corresponding responsibility to only distribute or dispense controlled substances pursuant to a prescription for a legitimate medical purpose and in the usual practice of pharmacy, actions for which Defendants are liable.

A. DEFENDANTS ARE SUBJECT TO PART C OF THE CSA

Section 842(a)(1)'s applicability to a person "subject to the requirements of part C" of the CSA simply refers to those persons who must obtain a DEA registration based on their activities with controlled substances. *See* 21 U.S.C. §§ 821-31 (Part C addresses "Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances"). At all times relevant to the complaint and currently, Shaffer Pharmacy held DEA registration number AS8550243. Carter Decl. Ex. C. As agents and employees of Shaffer Pharmacy, Thomas Tadsen and Wilson

Bunton are not required to have a separate DEA registration "if such agent or employee is acting in the usual course of his business or employment." 21 U.S.C. § 822(c)(1).

Shaffer Pharmacy and its pharmacists can clearly be held liable under the CSA for the acts of its pharmacist-employees in filling controlled-substance prescriptions. *United States v. Appalachian Regional Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1189-90 (E.D. Ky. 2017) (there is "nothing inconsistent about articulating the responsibilities of individual practitioners and pharmacists while simultaneously indicating that other entities may be subject to penalties for their role in issuing and filling invalid prescriptions," and denying corporation's motion to dismiss) (citing *United States v. Poulin*, 926 F. Supp. 246, 252-53); *see also Cty. of Lake v. Purdue Pharma, L.P.*, No. 1:17-MD-2804, 2020 U.S. Dist. LEXIS 141028, at *80 (N.D. Ohio, Aug. 6, 2020), *recons. denied sub nom. In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2020 U.S. Dist. LEXIS 173997 (N.D. Ohio, Sept. 22, 2020) ("Both pharmacies and pharmacists are practitioners under the [CSA]," and both are responsible for the improper dispensing of controlled substances.)

B. DEFENDANTS DISTRIBUTED OR DISPENSED CONTROLLED SUBSTANCES THAT ARE PRESCRIPTION DRUGS

The CSA defines both "distribute" and "dispense" to include the delivery, "the actual . . . transfer," of a controlled substance to a patient. *Compare* 21 U.S.C. § 802(11) (defining "distribute" as "to deliver (other than by administering or dispensing) a controlled substance") *and* 21 U.S.C. § 802(10) (defining "dispense" as including "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner"), *with* 21 U.S.C. § 802(8) (defining "deliver"). A pharmacist's filling a prescription order clearly constitutes distributing or dispensing under the CSA. Each controlled substance dispensed is also a prescription under the FDCA, 21 U.S.C. § 301 *et seq.*

C. DEFENDANTS' OBLIGATIONS UNDER THE CSA

1. Pharmacists and Pharmacies have a Corresponding Responsibility to Distribute or Dispense Controlled Substances Where there was a Legitimate Medical Purpose

Pharmacies and Pharmacists exercise a "corresponding responsibility" for the proper dispensing of controlled substances and must not knowingly fill an unlawful prescription. 21 C.F.R. § 1306.04(a). A pharmacist who "knows or has reason to know that the prescription was not written for a legitimate medical purpose" must not fill the prescription. *Medicine Shoppe-Jonesborough v. Drug Enforcement Admin.*, 300 Fed. Appx. 409, 412 (6th Cir. 2008) (quoting *Medic-Aid Pharmacy*, 55 Fed. Reg. 30,043, 30,044 (DEA July 24, 1990)).

"There is no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances." *Cty. of Lake*, 2020 U.S. Dist. LEXIS 141028, at *87. To assess if a pharmacy violated its corresponding responsibility when dispensing controlled substances the focus is on whether "a red flag was or should have been recognized at or before the time the controlled substances was dispensed," and if so, whether the red flag was "resolved conclusively prior to the dispensing of the controlled substance." *Id.* at *87-88. To evaluate whether a pharmacist knowingly filled a prescription in violation of the pharmacist's corresponding responsibility, courts look to whether the pharmacist ignored red flags that were present. As the Sixth Circuit explained:

> The regulation thus requires "pharmacists [to] use common sense and professional judgment," which includes paying attention to the "number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment," the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse.

Medicine Shoppe-Jonesborough, 300 Fed. Appx. at 412 (quoting *Ralph J. Bertolino Pharmacy, Inc.*, 55 Fed. Reg. 4,729, 4,730 (DEA Feb. 9, 1990)). Courts have also considered red flags to be: the combination of prescriptions from the prescriber; early refills; and a prescriber writing the

same prescriptions to patients with the same last name and address. *Pharmacy Doctors Enterprises, Inc. v. Drug Enforcement Admin.*, 789 Fed. Appx. 724, 730 (11th Cir. 2019).

2. Pharmacies and Pharmacists had an Obligation to only Distribute or Dispense Controlled Substances in the Usual Course of Pharmacy Practice

Pharmacists and pharmacies may only fill a prescription when the pharmacist is "acting in the usual course of his professional practice . . . ." 21 C.F.R. § 1306.06. *See United States v. Seelig*, 622 F.2d 207, 210-211 (6th Cir. 1980) (affirming a criminal conviction for violation of DEA regulations and ruling that "the allegation of distribution in violation of § 841(a)(1) includes the legal definition that the drugs were not dispensed, i.e., distributed in the usual course of professional practice"). Defendants were not acting in the usual course of professional pharmacy practice when it knowingly dispensed prescriptions for controlled substances when it knew or had reason to know that there was no legitimate medical purpose to do so.

D. DEFENDANTS VIOLATED THE CSA

From between 2015 and 2019, Shaffer Pharmacy purchased hundreds of thousands of dosage units of schedule II and III controlled substances. Carter Decl. ¶¶ 31-36, 69, 73, 76, 78, 90. There are numerous other pharmacies in Toledo and the surrounding county; Shaffer Pharmacy's purchasing volume, in dosage units, of schedule II and III controlled substance stands out. The orders were so suspicious, in fact, that one of Shaffer Pharmacy's distributors terminated controlled substance sales to Shaffer Pharmacy on November 21, 2019. Carter Decl. ¶ 94.

An expert pharmacist, Dr. Carl Gainor, reviewed Shaffer Pharmacy's dispensing records and found that Shaffer Pharmacy was not dispensing controlled substances in accordance with recognized pharmacy standards. *See generally* Declaration of Carl Gainor ("Gainor Decl."). A

chart of all the prescriptions that Dr. Gainor found to be dispensed without a legitimate medical use is attached as Exhibit 1 to the Declaration of Kendall A. Miller.

One example of how Defendants failed to meet its corresponding responsibility to ensure the legitimacy of prescriptions prior to dispensing include over three years of filling high doses of oxycodone for Patient M. J.-P. The U.S. Centers for Disease Control ("CDC") recommends avoiding or carefully justifying doses beyond 90 morphine milligram equivalent ("MME"). Gainor Decl. ¶ 18. Beginning in 2016, for a four year period, Defendants were dispensing prescriptions to M. J.-P. at 200 MME per day, over twice the dangerous dose. *Id.* ¶ 28.

In addition to the high daily MME dispensed for an extended duration, Defendants dispensed combinations of drugs that are not medically recommended. Shaffer Pharmacy dispensed prescriptions for opioids, benzodiazepines, muscle relaxants, and sedatives; a dangerous combination of drugs that is often associated with drug abuse.

Defendants regularly dispensed combinations of drugs that are highly unlikely to serve a legitimate medical purpose. There are several drug combinations sought after for the non-medical purpose of increasing the euphoric effects of opioids. Defendants filled the following dangerous combinations: an opioid, a benzodiazepine, and carisoprodol (known as the Trinity); an opioid, a benzodiazepine, and stimulant; and an opioid, a benzodiazepine, a muscle relaxant, and a sedative. The number of patients receiving these combination prescriptions, and the number of times Shaffer Pharmacy filled highly abused drug combinations, is alarming. *See* Carter Decl. ¶¶ 49-53.

Another red flag frequently undetected by the pharmacists at Shaffer Pharmacy was duplicative opioid therapy. Signs of duplicative therapy are easy to detect and exist when a patient is issued two or more prescriptions known to treat the same condition in the same

manner, such as concurrently dispensing multiple short-acting opioids to the same patient. *See* Gainor Decl. ¶ 18. For example, Defendants, over a four-year time span, dispensed multiple short-acting opioids in addition to long-acting opioids to Patient N.W. Gainor Decl. ¶ 32. As a result, Patient N.W. was receiving doses in excess of 1,900 MME per day for close to four years beginning around March 2016. *Id.* Doses in this range are reserved for the "most serious acute pain, such as terminal cancer, but such patients seldom survives for almost four years." *Id.*

Doctor Gainor reviewed over 3,000 records of dispensed prescriptions corresponding to twenty patients, and only in one instance did the documented diagnosis code address the significant red flags associated with the drugs dispensed. *See* Gainor Decl. ¶ 12, 45. This one instance indicates that pharmacists at Shaffer Pharmacy had the ability to document the resolution of red flags and did so by noting a terminal cancer diagnosis. *See id.* This record indicates that Defendants knew of, and were capable of, resolving red flags. Yet, other than this one patient, the records reviewed lack any indicia that Defendants exercised their corresponding responsibility to ensure that prescriptions filled were for a legitimate medical purpose.

As a registered dispenser, Shaffer Pharmacy is required to collect and maintain dispensing data. Additionally, as a pharmacy registered in Ohio, it is obligated to conduct a prospective drug utilization review to examine the appropriateness of prescriptions before filling. Gainor Decl. ¶ 25. The dispensing data Dr. Gainor reviewed, which was available to Shaffer Pharmacy pharmacists prior to dispensing, revealed obvious red flags of diversion that were not addressed prior to dispensing. Gainor Decl. ¶ 25. Having the requisite red flag revealing data in hand, "yet doing nothing with, information about possible diversion would actually ***facilitate*** diversion." *Cty. of Lake*, 2020 U.S. Dist. LEXIS 141028, at *91-92 (emphasis in original).

IV. AN INJUNCTION WILL PREVENT DEFENDANTS' CONTINUED ILLEGAL DISTRIBUTING AND DISPENSING OF CONTROLLED SUBSTANCES AND THE RESULTING HARM.

A. DEFENDANTS' UNLAWFUL FILLING OF PRESCRIPTIONS HARMS THE COMMUNITY

1. Defendants have Contributed to the Opioid Crisis

Almost 450,000 Americans have died of an opioid overdose, including prescription and illicit opioids, from 1999 to 2018, and 128 people die every single day, according to the CDC. CDC, *Understanding the Epidemic*, March 19, 2020, available at https://www.cdc.gov/drugoverdose/epidemic/index.html. In 2018, the most recent year for which data is available, 3,764 Ohioans died from an unintentional drug overdose. Ohio Department of Health, *2018 Ohio Drug Overdose Data: General Findings*, 1, December 4, 2019, available at https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/violence-injury-prevention-program/media/2018-ohio-drug-overdose-report. While statewide deaths decreased, the deaths in Lucas County went up from 153 deaths in 2017 to 166 deaths in 2018. *Id.* at 11.

"Anyone who takes prescription opioids can become addicted to them. In fact, as many as one in four patients receiving long-term opioid therapy in a primary care setting struggles with opioid addiction." CDC, *Opioid Overdose*, Aug. 29, 2017, available at https://www.cdc.gov/drugoverdose/opioids/prescribed.html (citations omitted). In Ohio, prescribers wrote an average of two more opioid prescriptions per one hundred persons compared to the national average. National Institutes of Health, National Institute on Drug Abuse, *Ohio: Opioid-Involved Deaths and Related Harms*, April 3, 2020, available at https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/ohio-opioid-involved-deaths-related-harms.

2. The Scope of Defendants' Unlawful Conduct Likely Exceeds the Prescriptions Currently Known to the United States

While the United States' expert reviewed prescribing records associated with twenty patients, there is evidence that violations far exceed the scope currently known to the United States. DEA DI Carter identified hundreds of prescriptions that are suspicious because of the failure to either detect or resolve various red flags and indicators of diversion, including suspicious drug combinations, early refills, the number of patients who paid for opioids with cash but used insurance to cover other prescriptions, geographic distance between patients' home of record or prescribers' location and Shaffer Pharmacy, and overlapping prescription profiles of patients residing within the same household. *Id.* at ¶¶ 49-53, 55, 59-62, 54. DI Carter has also identified over 600 patients who received dangerous combinations of controlled substances. Carter Decl. ¶¶ 49-53.

In addition to the above-mentioned red flags, Shaffer Pharmacy ordered significantly more Subsys than any other pharmacy with the same zip, and purchased more Subsys than county, state, and national averages. Carter Decl. ¶¶ 90-93. In 2015, Shaffer Pharmacy purchased more Subsys than any other pharmacy in Lucas County and purchased close to eighteen times the amount of Subsys than the second highest purchaser in the county. *See id.* ¶ 92.

Subsys is a powerful fentanyl product that is approved only to treat breakthrough pain in cancer patients. Gainor Decl. ¶ 42. The widespread misuse and abuse of Subsys was made public in 2016 after several current and former executives and managers of Subsys' manufacturer, Insys Therepeutics, Inc., were indicted and convicted in 2019 of crimes related to the marketing of Subsys. Carter Decl. ¶ 82. Despite the well-known concerns about the misuse of Subsys, Defendants continued to dispense the drug in large quantities to patients, such as

Patient D.V., whose documented diagnosis code indicates that the drug was not prescribed for an approved medical use. *See* Gainor Decl. ¶ 42.

V. THE RELIEF REQUESTED IS TAILORED TO DEFENDANTS' CSA VIOLATIONS AND THE HARM CAUSED BY THOSE VIOLATIONS

This Court has ample authority to enjoin Defendants based on their CSA violations. *See* 21 U.S.C. §§ 843(f) and 882(a); *see also De Beers Consol. Mines v. United States*, 325 U.S. 212, 220 (1945) ("A preliminary injunction is always appropriate to grant intermediate relief of the same character as that which may be granted finally."). An injunction under section 843(f) should be "tailored to restrain" the CSA violations. 21 U.S.C. § 843(f)(3).

Courts have previously enjoined registrants who violated the CSA and limited their ability to further deal in controlled substances. *See Advance Pharm., Inc. v. United States*, 391 F.3d 377, 390, 400 (2d Cir. 2004) (injunction against pharmaceutical company); *United States v. Chemicals for Research & Industry*, 10 F. Supp. 2d 1125, 1130 (N.D. Cal. 1998) (preliminary injunction against company); *see also United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 496 (2001). Defendants repeatedly and unlawfully filled prescriptions for controlled substances and should be enjoined from further dealing in those substances.

VI. THE TEMPORARY RESTRAINING ORDER SHOULD BE ISSUED WITHOUT NOTICE

Federal Rule of Civil Procedure 65 permits a court to issue a temporary restraining order without notice if "specific facts . . . clearly show that immediate and irreparable injury, loss, or damage will result to the movant." Fed. R. Civ. P. 65(b)(1)(A). The immediate and irreparable harm to the government is the potential destruction of hard copy prescriptions and sign-in logs.

Shaffer Pharmacy maintains on-site hard copy prescriptions and paper sign-in logs. Carter Decl. ¶ 9. On January 14, 2020, the United States anticipates executing a search warrant to obtain certain records, including but not limited to these prescriptions and logs. The search

warrant, however, will not cover every single potentially illegal prescription. Moreover, the search warrant will cover only certain records located at the premises of Shaffer Pharmacy; additional records may be maintained off-site and be outside the scope of the warrant.

If Defendants are provided advance notice of this action and request for temporary restraining order, it may take steps to alter, delete, or destroy records within its possession, custody, or control related to its unlawful distributing and dispensing, causing irreparable harm to the United States. The United States anticipates notifying Defendants of this action and order during the search warrant execution. The United States thus requests this TRO be issued without advance notice and further asks that the Court Order Defendants to preserve all prescriptions and patient records. *See Gen. Ret. Sys. of the City of Detroit v. Onyx Capital Advisors, LLC*, No. 10-CV-11941, 2010 WL 2231885, at *3-4 (E.D. Mich. June 4, 2010).

CONCLUSION

The United States has established that Defendants have repeatedly and routinely violated the CSA, and that unless enjoined will continue to do so to the great detriment of their customers and the public. The evidence presented establishes that the United States has fully met its burden to obtain the requested injunctive relief. Therefore, based on the above, pursuant to the CSA, Federal Rule of Civil Procedure 65(a) and (b), and Local Rule 65.01, a temporary restraining order without notice and a preliminary injunction should be issued to enjoin Defendants from distributing or dispensing any controlled substances.

Respectfully submitted,

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